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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/075,811	02/12/2002	Paul M. Lefebvre	GI-35	8854
23524 7590 01/09/2007 FOLEY & LARDNER LLP 150 EAST GILMAN STREET P.O. BOX 1497 MADISON, WI 53701-1497			EXAMINER GORDON, BRIAN R	
			ART UNIT 1743	PAPER NUMBER
SHORTENED STATUTORY PERIOD OF RESPONSE		MAIL DATE	DELIVERY MODE	
3 MONTHS		01/09/2007	PAPER	

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary

Application No.

10/075,811

Applicant(s)

LEFEBVRE, PAUL M.

Examiner

Brian R. Gordon

Art Unit

1743

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 14 April 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 14,21-27,29-34 and 36-41 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 14,21-27, 29-34 and 36-41 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on April 14, 2006 has been entered.

Response to Arguments

2. Applicant's arguments filed April 14, 2006 have been fully considered but they are not persuasive.

As to claim 14 it is unclear as to exactly what applicant intends to claim (see 112 section below).

Applicant asserts Jones fails to disclose a controller that performs the specific functions of the controller as claimed by applicant. Broadly interpreted applicant's device includes two valves (which applicant has elected to name them respectively as injector and pump valves) that can move between two positions. Jones discloses two valve elements 16 and 38 and previously stated. The respective valves can also move between two positions. Jones discloses the entire device (including the valves) is automatically controlled via a programming device that may also be referenced as a controller. It appears that applicant is arguing that because Jones does not refer to the two positions to which the valve (16) moves as "loading" and "rinsing" positions the

device is not structurally equivalent. The examiner respectfully disagrees for one can reference these positions as one chooses. While Jones may reference the device is intended for mixing liquids, it is not precluded from the device being used in other processes. One can refer to the source container (40) as one chooses and the liquid therein can provide a "rinsing" function as it causes liquids, particles, residue, or any other material to mixed and/or removed as it passes through the system. An operator can program the controller of Jones to control the entire device in any order or manner which one chooses. As such, the device can be "operable" in such a manner as argued by applicant. The device of Jones comprises all of the structural components as required in the claims. The manner in which a claimed apparatus is intended to be employed does not differentiate the claimed apparatus from a prior art apparatus satisfying the claimed structural limitations. As such the previous rejections as based upon Jones are hereby maintained.

In view of applicant's remarks/amendment the previous rejections of the claims as based upon Rose et al. and Tseung are hereby withdrawn.

However, while the specification of Tseung may not specify the elements 56 and 57, one of ordinary skill in the art would clearly recognize the elements are valves each connecting three conduits. As such, it would have been obvious to recognize the valves may be of the conventional three-way type.

As to the 103 rejections Based upon Jones in view of Nohl, Munk, Heimberg, and Gilson et al. applicant basically presents the same argument, the secondary reference does not disclose a pump valve alternateable between first and second positions, for all

of the respective rejections. It should be noted the secondary reference were not employed to provide a showing of the pump valve, for Jones alone meets the limitation of the pump valve as explained above.

Claim Interpretation

3. The preamble of the claims refers to the device as "a liquid chromatography sample injection system". While applicant is allowed to reference the device as so desired, it examiner asserts the preamble does not further limit the device as being structure of a liquid chromatography device, for the claims do not positively recite any further analytical elements such as a column to limit the device to such a system. Therefore, a device in any other field that meets the elements of device positively recited after the transitional phrase may be applied.

Claim Rejections - 35 USC § 112

4. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 14, 21-27, 29-34, 36, 39, and 41 are rejected under 35 U.S.C. 112, first paragraph, as based on a disclosure which is not enabling. The probe drive system comprising an arm is critical or essential to the practice of the invention, but not included in the claim(s) is not enabled by the disclosure. See *In re Mayhew*, 527 F.2d 1229, 188 USPQ 356 (CCPA 1976).

As to claim 14 it is unclear as to exactly what applicant intends to claim (see 112 section below). It is unclear if applicant intends to claim the probe drive system as an

element of the injector system. However in view of claim new claim 39 it appears as if applicant does not intend to claim the drive system as an element of the invention of claim 14. In the previous version of the claims the probe drive system was clearly required. The probe cannot be mounted to an arm of the drive system for the drive system is not required. If the drive system is not required the arm of the drive system is also not required hence the probe cannot be connected to arm nor the valve mounted on the arm. The probe drive system comprising an arm is essential to the invention as clearly illustrated by the disclosure and previous versions of the claims.

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. Claims 31 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 31 is not considered further limiting. The claim does not disclose any further structure but specifies how what function intends for the mobile phase to provide when the device is in use. Furthermore "a sample analyzer" is not claimed as element of the invention as any interaction with an unclaimed element is not considered further limiting. It is suggested applicant amend the dependency of the claim to claim 23 and amend "a sample analyzer" to "the sample analyzer".

Claim Rejections - 35 USC § 102

7. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

8. Claims 14, 21-22, 26, 29, 31-32, and 36, 38-40 are rejected under 35 U.S.C. 102(b) as being anticipated by Jones.

Jones et al. discloses an apparatus which includes a sampling head adapted to be mounted at a sample pickup station. The head includes a hollow sample pickup probe adapted to be inserted into a sample container at the sample pickup station for extracting a given amount of fluid sample from the container. The pickup probe is movable between a first or sampling position and a second or retracted position by means of an air cylinder. A valve mechanism connected to the probe is operable on movement of the probe to the sampling position for connecting the probe to a device for withdrawing fluid from the sample container through the probe. The air cylinder not only moves the probe but also, and at the same time, operates the valve mechanism. In the second position the valve mechanism effects fluid connections for mixing a given amount of the fluid sample with another fluid and for simultaneously transferring the mixture to a receptacle (abstract).

When a sample arrives at the sample pickup or aspirating station where one of the sampling heads is located and assuming that the analysis calls for the sample to be mixed with a diluent or a reagent, the probe dips down into the sample, sucks up a quantity of sample, and then withdraws from the cup. During these movements, the diluent or reagent is first drawn into a pump, second, mixed with a specific volume of sample and third, delivered by means of a conduit or tubing to a reaction tube apart from the sampling head. All of this is done **automatically** after which the sampling head is ready for the next cup to come along.

The device comprises a **programming device 14 (controller)** for controlling the automatic operation thereof.

The sampling head 12 includes a **valve mechanism 16 (injector valve mounted on arm 56)** defined by first and second valve blocks 18 and 20 respectively, linearly movable (slidable) relative to each other between two valve positions, namely, a sampling position and a delivery position (loading and injecting positions).

The **probe 22** and the valve mechanism 16 the probe 22 is connected through the valve blocks 18 and 20 and a **sample loop 34** to a **sample pump 36** for withdrawing some of a liquid sample from the cup 24. The pump 36 is operated by a valve 38 (pump valve) connected to the sources 30 and 32 of pressure and vacuum and controlled by the device 14. In this way a given amount of sample is drawn, i.e., aspirated from the cup 24 and into the sample loop 34. At the same time, a **source 40 of reagent (pressurized source of liquid mobile phase/dilutant)** is connected through the valve blocks 18 and 20 to a reagent pump 42 which is operated by a valve 44 connected to the sources 30 and 32 of pressure and vacuum for filling the pump 42 with a quantity of reagent. The valve 44 is also controlled by the device 14.

When the valve mechanism 16 is in the second or delivery position, one end of the sample loop 34 is connected through the valve blocks 18 and 20 to the reagent pump 42. The other end of the sample loop 34 is then connected to a conduit or tubing 50 leading to a receptacle 52, such as a reaction test tube. A shunt passage hereinafter to be described in detail shunts some of the reagent around the sample loop 34 to the outlet end of the loop 34 where it mixes with the sample being ejected from the sample

loop 34 by the pressure of the reagent stream at the inlet end of the loop 34. In this way, the given amount of sample is simultaneously ejected from the sample loop 34, mixed with the reagent and delivered in a reagent-sample mixture to the reaction test tube 52 (analyzer). In the tube 52, the reagent reacts with the liquid sample and after a predetermined period of time the resulting mixture may be subjected to colorimetric measurements. In the case of straight dilution, the resulting mixture may be subjected to counting, etc.

The cylinder 26 (motor) is operated to move the probe out of the cup 24 and to its retracted position and at the same time to move the valve blocks 18 and 20 relative to each other.

Claim Rejections - 35 USC § 103

9. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

10. Claims 30, 33, and 34 are rejected under 35 U.S.C. 103(a) as being unpatentable over Jones.

Jones does not specifically recite the length of the connection between the injection valve and the probe or that the injection valve is limited to four or six ports.

However it would have been obvious to one of ordinary skill in the art to recognize that the connection length between the valve and probe may have been any suitable length to ensure the probe adequately extends into the sample containers.

Furthermore, it would have been obvious to one of ordinary skill in the art at the time of the invention to recognize the number of ports may be limited as so desired by

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the operator. If additional testing is required or no testing at all, one may choose to add or exclude ports from the valve and employ the device for simply mixing or fluid transfer from one container to another.

11. Claims 23 and 33 are rejected under 35 U.S.C. 103(a) as being unpatentable over Jones as applied to claim 14 above, and further in view of Nohl et al., US 4,957,009.

Jones does not specifically recite the length of the connection between the injection valve and the probe or that the injection valve is limited to four or six ports. Nor does Jones specify the employment of a liquid chromatography column.

Nohl et al. discloses a pushloop liquid sampling method is an improvement in the method of introducing liquid samples into test equipment (such as for liquid chromatography) via a six port valve. The method involves pulling the sample completely past the sample loop in the six port valve and then pushing the desired amount of sample back into the sample loop (abstract).

It would have been obvious to one of ordinary skill in the art at the time of the invention to employ the six port valve when injecting fluids in a liquid chromatography column as taught by Nohl et al. in order to avoid errors and problems such as the introduction of bubbles within the sample loop.

12. Claims 23-25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Jones as applied to claim 14 above, and further in view of Munk, US 4,942,018.

Munk discloses a system for the generation of solvent composition gradients utilizes a packed bed gradient generator.

Figure 2 discloses an embodiment utilized to used to obtain a first set of experimental gradient profiles. This system was designed to generate a two-solvent gradient, and comprises a first metering pump 22 used to pump a first solvent 24 (solvent A) from a first storage reservoir 26 (reservoir A) and a second metering pump 28 used to pump a second solvent (solvent B) 30 from a second storage reservoir 32 (reservoir B) through packed bed gradient generator 10 into the sample injector 33 chromatographic column 34 and detector 36. Both metering pumps 22 and 28 may be of conventional design and numerous such pumps are readily available on the market. For example, an LDC-Milton Roy Simplex Mini-Pump Metering Pump can be used as metering pump 22 to pump solvent A 24 from reservoir A 26 and an LDC Milton Roy Constomeric III Metering Pump can be utilized to pump solvent B 30 from reservoir B 32. Detector 36 may be any commercially available chromatographic detector such as the Spectromonitor D detector (column 5, lines 20-39).

It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the device of Jones to incorporate the analysis column of Munk in order to identify and characterize the resultant mixture in a process in which the components of the mixture may be distinctly identified in a shorten analysis time period (column 1, lines 10-23).

13. Claims 27 and 28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Jones as applied to claim 14 above, and further in view of Heimberg et al., US 6,656,724.

Jones et al. does not disclose the probe is adjustable my comprising a drive system an X arm extending horizontally in an X direction; a Y arm slidably mounted on the X arm wherein the Y arm extends horizontally in a Y direction; and a Z arm slidably mounted on the Y arm wherein the Z arm extends vertically in a Z direction.

Heimberg et al. discloses a pipette apparatus comprising a pipette arm for pipetting sample substances and/or chemicals.

Figure 1 shows the device comprising a rectangular worksurface 2 having two face edges 2 and a front and rear longitudinal edge 4. Arranged on the worksurface 2 at its rear longitudinal edge 4 is a rear wall 6. Provided at the upper edge portion in the rear wall 6 is a horizontal rail 7 running parallel to the rear longitudinal edge 4 of the worksurface 2. Mounted traveling on the rail 7 in the longitudinal direction thereof (double-arrow 9, X direction) is a robotic arm 8.

The robotic arm 8 is arranged straight and rigid parallel to the face edges 3 of the worksurface 2, it thus standing perpendicular to the plane of the rear wall 6. The robotic arm 8 is outwardly defined by comprising two longitudinal walls 10 and a face wall 11 at its free end, the face wall being arranged U-shaped as viewed from above. Disposed between the two longitudinal walls 10 and spaced away therefrom is a rail 12. Mounted traveling on the rail 12 in the longitudinal direction thereof (Y direction) are three Z arms 13-15. Each of the three Z arms 13-15 extends vertically through a gap 16 between the rail 12 and the longitudinal side walls 10, two of the Z arms 13, 14 being arranged in the gap 16 or the like and the third Z arm 15 being arranged in the gap 16 on the right.

The robotic arm 8 is powered to travel along the rail 7 (X direction) and the Z arms 13 along (Y direction) and perpendicular (Z direction) to the rail 12 so that the Z arms 13-15 can cover substantially the complete area (X direction, Y direction) above the worksurface 2 and are height-adjustable (Z direction).

As to claim 28, as to the location of the valve it would have been obvious that the injection valve maybe located on either arm including the Z arm.

It would have been obvious to one of ordinary skill in art at the time of the invention to modify the device of Jones to incorporate the drive system of Heimberg et al. in order to allow the probe to access various size containers.

14. Claims 27, 28, 37, and 40 are rejected under 35 U.S.C. 103(a) as being unpatentable over Jones as applied to claim 14 above, and further in view of Gilson US 4,422,151 (as disclosed by applicant as the liquid handling system employed within applicant's invention, see page 4 of specification).

Jones et al. does not disclose the probe is adjustable my comprising a drive system an X arm extending horizontally in an X direction; a Y arm slidably mounted on the X arm wherein the Y arm extends horizontally in a Y direction; and a Z arm slidably mounted on the Y arm wherein the Z arm extends vertically in a Z direction.

Gilson discloses the 3-dimensional drive system as claimed by applicant including the probe holder in form of elements (26, 124).

It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the dispensing probe system of Jones et al. by incorporating the 3-

dimensional drive system of Gilson in order to allow for more mobility of the dispensing device.

15. Claims 14, 26-28, 31-32, and 36 are rejected under 35 U.S.C. 103(a) as being unpatentable over Tseung et al. US 2003/0099573.

Tseung et al. discloses a device that includes an X-Y-Z (probe drive system) robotic delivery system 22 that is capable of delivering bulk reagents, small supply reagents, buffer solutions, and air to the tissue specimens on the slides 12. The X-Y-Z robotic delivery system 22 includes a Z-head 24 that is controllably and selectively movable on a pair of linear motion assemblies, indicated generally by reference numerals 26a and 26b to any position in a horizontal X-Y plane. The Z-head 24 carries a vertically disposed probe 38, which is selectively and controllably movable up and down in a vertical, or Z, direction.

The device further includes an injector valve 57, a pump valve 56, and probe pump 46 (see Figure 4).

The operation of the robotic delivery system 22 is controlled by an autostainer control program implemented by the software of a control system 28. The hardware of the control system 28 is integrated into the chassis 14 of the autostainer 10 and includes a touchscreen display 30.

While the specification of Tseung may not specify the elements 56 and 57, one of ordinary skill in the art would clearly recognize the elements are valves each connecting three conduits. As such, it would have been obvious to recognize the valves may be of the conventional three-way type.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian R. Gordon whose telephone number is 571-272-1258. The examiner can normally be reached on M-F, with 2nd and 4th F off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill Warden can be reached on 571-272-1267. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



brg

**BRIAN R. GORDON
PRIMARY EXAMINER**